UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Arbor Pharmaceuticals, LLC,

Plaintiff,

v.

ANI Pharmaceuticals, Inc.

Defendant.

Case No. 0:17-cv-04910 (DWF-LIB)

PLAINTIFF'S STATEMENT OF THE CASE

Plaintiff Arbor Pharmaceuticals, LLC ("Arbor") respectfully submits its Statement of the Case pursuant to this Court's Notice of Assignment of Case For Jury Trial (Jun. 30, 2021) (Dkt. 183).

I. ARBOR'S CLAIMS FOR RELIEF

The Court is familiar with Arbor's claims for relief in light of its Order on Defendant ANI Pharmaceuticals, Inc.'s ("ANI") motions to dismiss, *Arbor Pharma., LLC v. ANI Pharma., Inc.*, No. 17-cv-4910, 2018 WL 3677923 (D. Minn. Aug. 2, 2018), and summary judgment Dkt. 160. In brief, Arbor asserts claims for false advertising and unfair competition under § 43(a)(1)(A) and (B) of the Federal Lanham Act, 15 U.S.C. § 1125(a)(1)(A) & (B), and under Minnesota law for ANI's violations of the Minnesota Unfair Trade Practices Act, Minn. Stat. § 325D.13, the Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. § 325D.44, and the Minnesota False Advertising Act, Minn. Stat. § 325F.67. *See* Complaint (Dkt. 1) (Oct. 30, 2017), at ¶¶ 41-55 & 63-83,

Arbors seeks damages, an accounting, and its fees and costs, and equitable relief, including corrective advertising. *See* Compl. at Prayer for Relief.

"When a commercial plaintiff assert[s] pendent state law claims under these Minnesota statutes in a Lanham Act trademark dispute," these "pendent claims 'are coextensive with the federal claims.'" *Buetow v. A.L.S. Enters., Inc.*, 650 F.3d 1178, 1183 (8th Cir. 2011) (quoting *DaimlerChrysler AG v. Bloom*, 315 F.3d 932, 935 n.3 (8th Cir. 2003)). The elements of Arbor's false advertising act include:

> (1) the defendant made a false statement of fact in a commercial advertisement about its own or another's product;
>
> (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience;
>
> (3) the deception is material;
>
> (4) the defendant caused its false statement to enter into interstate commerce; and
>
> (5) plaintiff has been or is likely to be injured as a result of the false statement.

Arbor, 2018 WL 3677923, at *2 (citing *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1180 (8th Cir. 1998))

Section 43(a)(1)(A) creates a separate cause of action for unfair competition. 15 U.S.C. § 1125(a)(1)(A); *Healthpoint Ltd. v. Rivers Edge Pharma., LLC*, No. 03-cv-0984, 2005 WL 356839, at *3 (W.D. Tex. Feb. 14, 2005). This Section allows a claim against

> Any person who, on or in connection with any goods or services . . . uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact which—is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, ***or approval of his or her goods***, services, or commercial activities by another person.

(emphasis added). "§ 43(a), 15 U.S.C. § 1125(a) is one of the few provisions [in the Lanham Act] that goes beyond trademark protection." *Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 29 (2003).

Arbor will demonstrate at trial that from September 27, 2016, until November 2, 2018, ANI falsely and misleadingly advertised and promoted its erythromycin ethylsuccinate for oral suspension antibiotic drug ("ANI's EES product") as FDA-approved and as an AB-rated equivalent to and generic substitute for Arbor's EryPed® and E.E.S.® Granules products. In fact, ANI's EES product was *not* approved by the FDA until November 2, 2018, at which point it was rated AB-equivalent to Arbor's products, and became a generic substitute for them. Arbor will also demonstrate that ANI engaged in unfair competition under Section 43(a)(1)(A) by falsely representing that its unapproved EES product was FDA approved. ANI's conduct caused injury to Arbor, and damages from lost sales and price erosion of approximately $70 million. At the same time, ANI garnered about $20 million in unjust enrichment profits, while also injuring Arbor's reputation.

II. FACTS ARBOR WILL PROVE AT TRIAL

Most, if not virtually all, of the key facts demonstrating ANI's liability for false advertising and unfair competition under the Lanham Act and Minnesota law are undisputed, and indeed indisputable. At trial, Arbor will establish that it researches, develops, and markets prescription drug products, including a prescription antibiotic known as erythromycin ethylsuccinate for oral suspension that Arbor offers under the brand names EryPed® and E.E.S.® Granules. Both EryPed® and E.E.S.® are approved

by the U.S. Food and Drug Administration ("FDA"), and have been ever since Arbor launched its products in 2011. During the time period relevant to this case—September 27, 2016 through November 2, 2018—Arbor's EryPed® and E.E.S.® products were the only FDA-approved erythromycin ethylsuccinate for oral suspension products available for dispensing in the U.S.

A. Overview of FDA-approval and generic equivalence

Through both lay and expert witnesses, including Arbor's pharmacology expert, Ms. Marsha Millonig, and its regulatory expert, Kalah Auchincloss, Arbor will provide a background of the regulatory and pharmaceutical marketing context of this case.

As this Court explained in its prior rulings, the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq*., requires FDA approval, through a new drug application ("NDA"), before a new drug may enter the interstate commerce. *Id*. § 355(a). A product essentially identical to an NDA-approved drug may be approved and marketed based on an Abbreviated New Drug Application, or "ANDA," which requires the manufacturer of the similar drug to demonstrate that the two drugs are therapeutically equivalent. 21 U.S.C. at § 355(j)(2)(A)(i)-(viii). If the FDA determines that a "Reference Listed Drug," or "RLD," and the ANDA product are therapeutically equivalent, it gives the ANDA product an AB-rating. An AB-rated ANDA product is called a "generic."

Generics make up the lion's share of prescription drugs sold in the United States. The FDA's "Orange Book," officially entitled "*Approved Drug Products with Therapeutic Equivalence Evaluations*," provides information about approved brand name and any approved generic equivalents. The Orange Book classifies Arbor's EryPed® and

E.E.S.® products as the RLD for erythromycin ethylsuccinate for oral suspension drug products. Accordingly, any generic erythromycin ethylsuccinate for oral suspension drug must be rated by the FDA as AB-equivalent to EryPed® or E.E.S.®. Between September 2016 and November 2018, the Orange Book identified no approved, actively marketed drug products that were AB rated or generic to EryPed® and E.E.S.®.

Generic drug companies, including ANI, achieve sales through pharmacist substitution. Generic drug manufacturers provide information about their products to large drug information databases (often called "compendia") including, for example, Medi-Span, which sells subscriptions to its database to distributors, wholesalers, pharmacies, and others. Generic drug manufacturers also provide information about their products directly to drug wholesalers, retail pharmacy chains, and other customers, including via an industry standard HDMA form that compares the generic to the RLD. Based on the information provided by the drug manufacturers, either directly or through the compendia or a wholesaler, retail pharmacies will link generic drugs to the RLD in their computer systems.

As ANI's own pharmacist expert, Steve Slovick, explained about links, "Someone types in the brand, the computer reads something else as a generic and spits out to dispense the generic from the pharmacy." Pharmacists thus will dispense the generic when presented with a prescription for the brand RLD when it is linked to the generic. E-prescribing systems—which are used to generate most of today's prescriptions—may also automatically change the brand name of a prescribed medication to that of an available generic when transmitting the script from the doctor to the pharmacy. Notably,

when there is more than one generic drug available, pharmacies will stock only *one* of the available generics.

Because generic drugs are dispensed through substitution, the importance of therapeutic equivalence cannot be overstated. Patients rely on the skill and knowledge of their physicians when taking prescribed drugs. When the physician writes a prescription, she relies on the pharmacist to dispense the drug that is prescribed. Pharmacists may substitute a generic drug for a particular branded product, but they do so based on the assurance that they are literally giving what the doctor ordered. Accordingly, pharmacies would not stock, and pharmacists would not dispense, drugs as "generics" if they knew either that a generic drug had not been approved by the FDA, or if a supposed generic was not, in fact, an AB-rated equivalent.

B. ANI buys a discontinued ANDA, and the FDA rejects ANI's CBE-30

In July 2015, ANI bought ANDA No. 62055 from Teva Pharmaceuticals ("Teva"), covering Teva's generic version of Arbor's RLDs (EryPed and E.E.S.). An ANDA can be active, discontinued, or withdrawn. By definition, a "discontinued" product is not being marketed, and thus cannot be active. Teva had discontinued making and selling its product in 2003. Teva's—and subsequently ANI's—EES product thus remained in the "discontinued" section of the Orange Book until after November 2, 2018.

Once a prescription drug has been discontinued, it cannot be marketed again until FDA deems it approved. As ANI admits, under FDA regulations, a company "cannot simply jump back into the market" with a discontinued product "using procedures, controls, specification, etc., that were previously approved . . . ." This is because, in

approving drugs, FDA considers not only the composition of a product, but also the processes used to manufacture, package, and test it.

The method of obtaining the FDA's approval for a drug product that has undergone changes since the initial ANDA approval depends on the nature of the change. The FDA must approve a "major" change to a product prior to marketing through a Prior Approval Supplement, or "PAS." 21 C.F.R. § 314.70(b) A company may enact moderate changes thirty days after a Changes Being Effected, or "CBE," notice to FDA, as long as FDA does not object to the changes or require a PAS. 21 C.F.R. § 314.70(c).

The FDA's Guidance for Industry assists drug companies in determining whether proposed changes are "moderate"—allowable under a CBE-30—or "major"—requiring a PAS. As advised by the FDA, "Major Changes" include a "move to a different manufacturing site." And here, ANI's manufacturing facility was not approved in Teva's ANDA. To manufacture its version of Teva's generic antibiotic, ANI used a different manufacturing facility that had never made this type of drug before. ANI also had to qualify new packaging and testing facilities. Thus, ANI had to validate both the manufacturing and packaging processes for a product in a form it had never before manufactured.

Additionally, this was the first time ANI used the erythromycin ethylsuccinate active pharmaceutical ingredient, or "API." The manufacturer ANI selected as its supplier of this API, Ercros, S.A., a Spanish drug company, was the successor to the company that had provided Teva with the erythromycin ethylsuccinate API for Teva's EES product. But since Teva had discontinued its EES product in 2003, it had "been a

number of years since Ercros ha[d] micronized Erythromycin Ethylsuccinate as there have been no customers for this grade for some time." The FDA thus had not reviewed the Drug Master File ("DMF") for the Ercros erythromycin ethylsuccinate API in many years.

Beyond its lack of recent experience with the erythromycin ethylsuccinate API, Ercros presented a host of problems as an API supplier. Ercros had received a serious Warning Letter from the FDA for its violation of current Good Manufacturing Practices, or "cGMP," which are practices incorporated into the FDA's regulations, and which must be followed to ensure that drug components are safe and effective. Ercros' violations of cGMP, which resulted in FDA classifying its drug products as "adulterated," included Ercros' failure to keep pests out of its facilities—a fact that "was confirmed by an FDA investigator who observed bird feathers in the plant and spiders" in an Ercros facility.

However, because Ercros was the successor to the API supplier identified in the original ANDA approval, ANI *had* to rely on the DMF for Ercros' erythromycin ethylsuccinate API to even think about launching its EES product based on a CBE-30. And so, despite considering Ercros a "high quality risk," ANI conditionally approved it as a supplier, and formulated its EES product with the Ercros API.

Thus, notwithstanding FDA's Guidance and ANI's plan to manufacture, test, and package a long-discontinued drug in new facilities with an unevaluated API from a troubled manufacturer, on August 26, 2016, ANI submitted to FDA a CBE-30, and not a PAS.

Where, as here, a company proposes multiple or complicated changes to a drug than what had previously been approved, the FDA is unlikely to complete its review and issue a final action within thirty days. Thus, in its Guidance for Industry, FDA advises drug companies that within thirty days after submission of a CBE-30, the FDA "will notify the applicant that prior approval is required for the change," but that "[i]t is unlikely that a substantive review and action letter will be completed within 30 days." This is consistent with controlling regulations, which only required the FDA to "inform" a petitioner within thirty days that a CBE-30 submission is not accepted. 21 C.F.R. § 314.70(c)(5).

Consistent with the regulations and Guidance, on September 16, 2016, twenty-one days after ANI's CBE-30 submission, Dr. Lisa Oh, a Regulatory Project Manager in FDA Office of Generic Drugs ("OGD") spoke with Ellen Camos, ANI's vice president for regulatory affairs, and told ANI that its CBE-30 was denied, and that prior approval was required for the changes ANI proposed. FDA further instructed ANI it could not market its EES product without FDA approval of a PAS.

On that same Friday evening, Dr. Oh and Ms. Camos exchanged emails concerning ANI's "questions about why this CBE-30 has been denied to PAS," and Ms. Camos agreed "it would be helpful for us if you can provide the agency's rationale for the conversion." The next Monday, September 19, 2016, the FDA followed up its verbal denial with a written denial of the CBE-30, explaining its rationale for requiring prior approval before ANI could market its EES product:

> Considering that (1) the new ANDA holder has no prior experience in the manufacture of "granules for oral suspension" products, and final dosage form is considered complex (oral suspension) (2) brand new DMF which has never been reviewed since it was submitted in 1998, the impact to the drug product is high, and (3) New specifications for dissolution have been added to the drug product specifications. Biopharm recommends PAS. Therefore, we recommend the supplement be denied CBE 30 to Prior Approval Supplement.

At the same time the FDA was explaining to Ms. Camos why ANI's CBE-30 had been denied, ANI had its lawyers begin a letter campaign to try and convince the FDA to reverse its decision. On September 19, 2016, ANI, through counsel at Buchanan Ingersoll & Rooney, wrote FDA's OGD Director to complain that "requiring a PAS is inappropriate," and would allow a "monopoly on this product" to continue. ANI's counsel again wrote the OGD Director the following day, acknowledging receipt of Dr. Oh's September 19 correspondence "formally denying ANI's CBE30 and recommending a PAS be submitted instead." Despite acknowledging FDA's "formal" and timely denial of the CBE-30, ANI's counsel again requested the CBE-30 be allowed.

On December 16, 2016, the FDA again denied ANI's CBE-30, explaining in even greater detail why ANI's CBE-30 had been "DENIED TO PAS." The FDA noted ANI had sought approval for "a new manufacturing and testing facility" in Baudette, Minnesota, another "new packaging and testing facility" in Puerto Rico, and "[t]wo new analytical testing facilities" in Oakdale, Minnesota and Puerto Rico. The FDA explained that, among other reasons, the CBE-30 was denied because "a move to a different manufacturing site that results in a 'restart' at the new manufacturing site of a type of operation that has been discontinued for more than two years [is] a major change, thus

requiring a PAS." The FDA also instructed ANI it could ***not*** market its erythromycin ethylsuccinate drug product without FDA approval of a PAS: "FDA concludes the changes described [in the CBE-30] are not permitted to be put into effect without advanced approval of the supplement . . . ." ANI acknowledges this was a "definitive rejection the CBE-30," and that FDA never "reversed that decision and concluded that a CBE-30 would be okay[.]"[1]

C. ANI submitted a PAS in December 2016, which FDA approved about two years later

ANI finally submitted a PAS for its EES product on December 22, 2016. The FDA approved it on November 2, 2018. During that intervening nearly two-year long period, the FDA twice rejected ANI's PAS as deficient, and ultimately required ANI to prove, through a bioequivalence study, that ANI's EES product is actually an AB-rated equivalent to the RLD—that is, a generic to Arbor's products.

The FDA first rejected ANI's PAS in its September 20, 2017 Complete Response letter. There, the FDA identified "MAJOR" deficiencies, including the inadequacy of the DMF for the Ercros API. The FDA also concluded ANI must conduct bioequivalence testing, and again told ANI not to market its antibiotic until the PAS was approved.

[1] A primary theme of ANI's defense in this action has been its contention that the FDA did not "formally" deny ANI's CBE-30 within thirty days of its August 26, 2016 submission. But beyond the plain language of the regulations and the FDA's Guidance, ANI admits that no law imposes a "formality" requirement on FDA. ANI also could provide no defining characteristic of a "formal" denial. As Arbor will show, the facts and the law are clear that the FDA's rejection of ANI's CBE-30 was effective when first communicated on September 16, 2016.

On February 14, 2018, ANI submitted its first Resubmission Major Complete Response Amendment. On May 25, 2018, FDA again required ANI to provide a "Major Amendment," explaining it again found the DMF for the API "inadequate with Major deficiencies." The FDA again warned ANI: "This drug product may not be marketed without final agency approval under section 505 of the FD&C Act."

On August 7, 2018, ANI submitted its second Resubmission Major Complete Response Amendment. FDA finally approved the PAS on November 2, 2018.

D. ANI launches its unapproved EES product on September 27, 2016, but ANI concealed from the FDA it was actively marketing its EES product

Despite FDA's denial of its CBE-30, ANI launched its unapproved EES product on September 27, 2016. ANI insists that, despite FDA's rejection of its CBE-30 and express requirement of prior approval before ANI would be allowed to market its EES product, the FDA nevertheless knew that ANI was marketing its EES product from September 27, 2016, until the PAS was finally. But as the evidence will show, this is both unsupported and false.

ANI admits it never "formally" told the FDA's Office of Generic Drugs that it was marketing its EES product despite the FDA's denial of the CBE-30 and requirement of a PAS. In fact, and to the contrary, ANI consistently misled the FDA, and indicated that it was *not* marketing its EES product.

In its PAS submissions and various requests for expedited review ANI submitted to the FDA throughout the period it was marketing its unapproved EES product, ANI told the FDA that erythromycin ethylsuccinate is a "sole-sourced" product offered only by

Arbor, and that granting the PAS would allow ANI to begin marketing the first generic. These representations were false; there was no "monopoly" because ANI had been selling its drug since September 2016. ANI never reached out to FDA to correct the record. Instead, ANI lied to FDA, and intentionally concealed from the FDA that ANI was marketing an unapproved drug pending agency consideration of a Prior-Approval Supplement.[2]

ANI's conduct during the FDA's May 2017 pre-approval inspection of ANI's Baudette facility is particularly telling—and egregious. During that inspection, David Sullivan, ANI's vice president of Quality Operations, told the FDA's inspector that batches of ANI's EES product "produced after the Firm's Official notification from the Agency to change the CBE-30 to a PA[S] are on hold awaiting an Agency determination on the PA[S]." That was a falsehood; the EES product was not on hold. Rather, as Art Przybyl, ANI's then president testified, ANI continued to manufacture, market, and sell its EES product throughout the period from September 27, 2016, through November 2, 2018. And Mr. Sullivan admitted the "hold" only existed *during* the inspection, after which the product was released for distribution long before the PAS was ultimately

[2] ANI also made misrepresentations to the Orange Book staff, claiming it launched its EES product "based on the submission of a CBE-30," without disclosing that the OGD had denied the CBE-30 and required a PAS, or that ANI had submitted a PAS which remained pending. In that same correspondence, ANI advised the Orange Book staff that "the most stringent of" ANI's "revisions" to the manufacturing changes of the EES product "is classified as moderate." But in denying ANI's CBE-30, the OGD classified ANI's revisions as a "major change requiring a PAS."

approved. Mr. Sullivan further admitted that ANI never told FDA it was releasing its product from its supposed "hold" before approval.

Thus, until the FDA finally approved ANI's PAS in November 2018, the FDA considered ANI's EES product to be "discontinued," and did not include it as an AB-rated equivalent in the Orange Book. Instead, the FDA continued to list Arbor's EryPed® and E.E.S.® as products "for which the FDA has not approved an ANDA referencing that NDA drug product" in FDA's List of Off-Patent, Off-Exclusivity Drugs Without an Approved Generic. Moreover, under PDUFA, Arbor paid substantial fees based on the status of EryPed® and E.E.S.® as "sole-source" products—that is, drugs *without* generic competition. In fact, however, Arbor was losing tens of millions of dollars in sales due to ANI's false advertising of its product as an approved, AB-rated "generic." Arbor wrote to the FDA, advising it of these unusual (and unfair) circumstances, and asked FDA to waive the PDUFA fees. FDA denied Arbor's waiver request, explaining it lacked discretion to waive the fees because, as of October 1, 2018, ANI's product remained "discontinued," and Arbor's "EryPed and E.E.S. products listed in the Orange Book were not designated as being therapeutically equivalent to an approved product."

E. ANI falsely advertised is EES product as FDA approved and an AB-rated equivalent, when it was neither

At the same time ANI was misleading the FDA and assuring it that the EES product was "on hold," ANI was also telling its customers—falsely—that its EES product was an FDA-approved and AB-rated generic for Arbor's EryPed® and E.E.S.® products.

And ANI also never told its customers that its CBE-30 had been rejected and its PAS had not yet been approved.

In September 2016, before the launch of its EES product, ANI began advertising and promoting its EES product to its (and Arbor's) customers. Relying in part on the industry-standard HDMA form, ANI represented to customers, including distributors and pharmacy chains, that its product was FDA-approved and rated AB equivalent to Arbor's E.E.S.® product. ANI's advertising targeted customers to ensure ANI's product would be "linked" to Arbor's in customer databases and computer systems that pharmacists use to make drug dispensing decisions, as a generic equivalent to the Arbor brand product.

In its advertising and promotions, ANI expressly told its customers that its EES "product is approved." When asked direct questions about the status of its drug, ANI relied on its CBE-30 submission, concealing that FDA had already rejected it and required a PAS. In fact, ANI expressly stated, after the FDA had twice rejected ANI's CBE-30, that "because we did not hear any objection from the FDA, we can launch today," and further claimed that: "It may take a little time before the FDA website is updated to change the ANDA from discontinued to active status."

ANI never told *any* of its customers that the CBE-30 had been denied. ANI also never told any pricing services that its product was *not* AB-rated, and instead told them all that it was. To the contrary, when Arbor tried to set the record straight, ANI—relying on its outside counsel—launched a disinformation campaign, accusing Arbor of being "incorrect," and insisting that ANI launched its AB-rated and FDA approved drug because Arbor had a "monopoly" on EES products.

ANI's letters, labeling, promotional emails, HDMA forms, and other information it provided to distributors, pharmacies, and databases constitute "advertising and promotion" under § 43(a). E.g., *POM Wonderful LLC v. Coca Cola Co.,* 134 S. Ct. 2228, 2233-34 (2014) (false advertising claims could proceed based on defendant's labeling of its beverage); *Alpharma, Inc. v. Pennfield Oil Co.,* 411 F.3d 934, 937-38 (8th Cir. 2005) (reinstating claims that ads and labels falsely promoted antibiotic as FDA approved); *Healthpoint, Ltd. v. Ethex Corp*., 273 F. Supp. 2d 817, 844-47, n.141 (W.D. Tex. 2001); *Sirius Labs, Inc. v. Rising Pharm., Inc.,* Case No. 03-cv-6965, 2004 WL 51240, at *4 (N.D. Ill. Jan. 7, 2004). Such "false descriptions of a product, contained in the product's label, share with newspaper advertisements and television and radio commercials the ability to engender consumer confusion both as to the origin and content of that product[.]" *Warren Corp. v. Goldwert Textile Sales, Inc.*, 581 F. Supp. 897, 900 (S.D.N.Y. 1984). Moreover, there is no reasonable dispute that the materials were "sufficiently disseminated" to constitute advertising or promotion. *Porous Media Corp. v. Pall Corp*, 173 F.3d 1109, 1121 (8th Cir. 1999) (sending advertising to five recipients was sufficient dissemination); *citing with approval Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379, 1386 (5th Cir. 1996) ("even a single promotional presentation to an individual purchaser may be enough to trigger the protections of the Act.")[3]

[3] ANI has admitted that its advertising and EES product were in "interstate commerce," and Arbor does not believe that this element is in dispute.

F. ANI's advertising was false, deceptive, and material

ANI's advertising and promotions were *false*. A "false statement" may be either "literally false as a factual matter" or "literally true or ambiguous but which implicitly convey a false impression, are misleading in context, or are likely to deceive consumers." *Arbor*, 2018 WL 3677923, at *2. Here, ANI's advertising and promotion during the relevant period of its product as an FDA-approved, AB-rated generic substitute for Arbor's products was *literally* false, because the FDA did not in fact approve ANI's PAS until November 2, 2018, at which point it was assigned its AB-rating.

"Proof of literally false advertising entitles a plaintiff to ***a presumption of actual consumer deception and the fact of harm***." *Solvay Pharm., Inc. v. Global Pharm.*, 419 F. Supp. 2d 1133, 1144 (D. Minn. 2006) (emphasis added) (citing *Porous Media Corp. v. Pall Corp*., 110 F.3d 1329, 1333 (8th Cir. 1997) (approving "a presumption of causation and injury . . . that upon a finding that the defendant deliberately deceived the public [the jury] could assume that the defendant's statements caused harm to the plaintiff, satisfying the fifth element of the cause of action")); *see also United Indus.*, 140 F.3d at 1180 ("If a plaintiff proves that a challenged claim is literally false, a court may grant relief without considering whether the buying public was actually misled; actual consumer confusion need not be proved.")

This presumption is even stronger where, as here, ANI's false advertising falsely *compares* its EES product to Arbor's products, including, for example, in its HDMA form submissions. E.g., *Buetow v. ALS Enterpr. Inc.*, 650 F.3d 1178, 1183 (8th Cir. 2011) ("when a competitor's advertisement, particularly a comparative ad, is proved to be

literally false, the court may presume that consumers were misled and grant an irreparably injured competitor injunctive relief without requiring consumer surveys or other evidence of the ad's impact on the buying public") (reversing grant of injunctive relief where District Court also presumed that harm was "irreparable").

Because ANI's advertising was literally false, the "deception" element of Arbor's Lanham Act false advertising claim may be presumed. *Porous Media*, 110 F.3d at 1333. But the evidence also will show beyond any doubt that ANI's false advertising deceived customers, and led them to purchase and dispense ANI's EES product rather than Arbor's EryPed® and E.E.S.®. As ANI's expert, Mr. Slovick, testified: "I don't believe a pharmacist would knowingly distribute a product that was not approved."

These facts are further shown by Arbor's survey evidence. Expert Hal Poret surveyed 400 pharmacists, and 89.3% answered that their decision to dispense a generic would be impacted if it "did not have an active FDA approval." And 91.5% found that an AB-rating would impact their decision to dispense:

Summary Table – Much Less/Somewhat Less Likely (Bottom 2 Box) How would it impact your decision about whether or not to dispense the generic substitute if the generic substitute…			
The generic substitute …	E.E.S. 200 MG/5 ML GRANULES (N=200)	EryPed 200 MG/5 ML SUSPENSION (N=200)	Total (N=400)
…is not AB-rated to the brand	92.0% 184	91.0% 182	91.5% 366
…did not have an active FDA approval	87.0% 174	91.5% 183	89.3% 357

In his Rebuttal survey, Mr. Poret tested the impact of active FDA approval and AB-rating to pharmacists' dispensing decisions, irrespective of substitution, again

confirming that the lack of an active FDA approval or an AB-rating impacts pharmacists' dispensing decisions:

Summary Table – Much Less/Somewhat Less Likely (Bottom 2 Box) How would it impact your decision about whether or not to dispense the generic product if the generic product…			
The generic product …	EES (N=100)	ERYTHROMYCIN ETHYLSUCCINATE (N=100)	Total (N=200)
…is not AB-rated to the brand	88	87	87.5% 175
…did not have an active FDA approval	87	80	83.5% 167

The evidence is overwhelming that ANI's customers would not have purchased and dispensed ANI's unapproved and unrated products had ANI not deceived them.

In addition to actual deception, the facts at trial will demonstrate that ANI's false advertising statements were *material*. A false advertising statement is material if it is "likely to influence buying decisions." *Porous Media*, 110 F.3d at 1332.

The evidence at trial will prove materiality, including Mr. Poret's survey. Mr. Poret's survey focused on whether FDA approval and AB ratings are important to pharmacists considering whether to dispense a generic EES product. As his testimony will illustrate, ANI's advertising and promotional statements were material because pharmacists would have been unlikely to dispense ANI's EES product if they knew it was not AB-rated or FDA approved.

Moreover, a misrepresentation about a product's inherent quality or characteristic is "material." *Select Comfort Corp. v. Baxter,* 996 F.3d 925, 938-39 (8th Cir. 2021); *see also Osmose, Inc. v. Viance, LLC*, 612 F.3d 1298, 1319 (11th Cir. 2010) (allegedly false statements regarding "safety and efficacy" of treated wood products went to "inherent

quality"). The regulatory status of a prescription drug is an "inherent quality" of the product, and likely to influence the purchasing decisions of wholesalers and retailers. *N. Am. Med. Corp. v. Axiom Worldwide, Inc.*, 522 F.3d 1211, 1226 (11th Cir. 2008) (false representations regarding physiotherapeutic spinal device, including manufacturer's purported affiliation with NASA and product's alleged FDA approval, "logically would influence a doctor's decision to purchase the DRX 9000 over a competing machine without those qualities").

Finally, "a deliberately false or misleading statement that was comparative or implicated a competitor or its product" is presumptively material. *Select Comfort*, 996 F.3d at 938. And again, ANI deliberately and falsely compared its EES product to Arbor's products, claiming that its EES product had been rated as AB-equivalent to Arbor's, when it had not.

G. ANI's false advertising and unfair competition injured Arbor

"[I]n comparative advertising cases where money damages are sought and where there exists proof of willful deception, as here," the Court may presume "causation and harm to the plaintiff." *Porous Media*, 110 F.3d at 1336. This presumption is particularly appropriate because this is a *two-competitor* market. *Robroy Indus.-Tex., LLC v. Thomas & Betts Corp.*, No. 15-cv-0512, 2017 WL 1370545, at *5 (E.D. Tex. Apr. 10, 2017).

And here, the evidence will show that ANI's false advertising worked. Medi-Span, one of the largest drug databases in the industry, linked ANI's product to Arbor's as an "AB" rated generic immediately after ANI's September 2016 launch. ANI's EES product

also was linked to Arbor's EryPed® and E.E.S.® products as "equivalent" by distributors, including one of the largest in the industry, McKesson.

Once a generic prescription drug launches, sales of the brand name drug can be expected to decrease sharply. To offset these losses, Arbor launched its own "authorized generic" version of its products. But even with its competitively priced authorized generic, Arbor lost unit sales to ANI. Through its false advertising of its product as an FDA-approved, AB-rated generic equivalent for Arbor's products, ANI "won the bids" as the preferred generic for AmerisourceBergen Corporation, Walgreens, CVS, Caremark, Econdisc, Publix, OptiSource, H.D. Smith, and H-E-B.

Part of ANI's successful marketing strategy for its EES product was to have it placed in distributors' "auto substitution" programs. ANI "approached all of the major potential customers" as "the first generic back to market for the brand . . . ." Thus, ANI was part of AmerisourceBergen Corporation's ("ABC") auto substitution program immediately following launch, and stayed in the program thereafter. This "meant that if a customer was using ABC's Progenerics program, they would automatically substitute [ANI's EES] product for any other generic."

While ANI achieved many of its sales through substitution, *all* of its sales during the relevant period were at Arbor's expense. In this two-competitor market for a *prescription* drug, pharmacists were required to dispense either Arbor's FDA-approved drug, or ANI's unapproved drug. And because pharmacies would not have stocked and dispensed ANI's EES product had they know that it was unapproved, all of ANI's sales of its falsely advertised drug necessarily came at Arbor's expense. Irrespective of

whether a doctor wrote the brand name or "erythromycin ethylsuccinate" on a prescription, ANI's drug would not have been purchased by distributors, sold to retailers, stocked at pharmacies, and dispensed by pharmacists—through substitution or otherwise—but for ANI's false advertising.

While ANI's goal was to achieve 100% substitution, it settled for between 55% and 65% of the market. In short, during the period ANI falsely advertised its EES product as an FDA-approved, AB-rated generic substitute for Arbor's products, Arbor's sales dropped by over half, and it suffered price erosion on the sales it did make.

H. Arbor is entitled to damages

Once the fact of injury has been established, "a lesser standard of proof is applicable to proof of the *amount* of damage." *Nat'l Farmers' Org., Inc. v. Assoc. Milk Prod., Inc.*, 850 F.2d 1286, 1293 (8th Cir. 1988). Thus, "[w]hen assessing these actual damages, the district court may take into account the difficulty of proving an exact amount of damages from false advertising, as well as the maxim that 'the wrongdoer shall bear the risk of the uncertainty which his own wrong has created.'" *Porous Media*, 110 F.3d at 1336 (other quotations and citations omitted).

Before launching its EES product in September 2016, ANI estimated that "[t]he current annual U.S. market for this product is approximately $78 million . . . ." In fact, as a result of ANI's false advertising and unfair competition, Arbor lost about $70 million between the time ANI began falsely advertising its product, and when the FDA approved its PAS in November 2018:

Arbor Pharmaceuticals, LLC v. ANI Pharmaceuticals, Inc.
Damages Summary

	Exhibit Reference	Sept - Dec 2016	2017	Jan - Oct 2018	Total
Arbor's Lost Profits					
Lost Profits from Lost Sales	**Exh 2**	$ 5,072,201	$ 22,486,652	$ 21,981,580	$ 49,540,433
Lost Profits from Price Erosion	**Exh 3**	357,095	11,352,848	9,219,040	20,928,983
Total Lost Profits		$ 5,429,296	$ 33,839,500	$ 31,200,620	$ 70,469,416

I. ANI should also disgorge its unjust enrichment

In addition to Arbor's recovery for damages due to lost profits, the Lanham Act allows for the disgorgement of the defendant's profits realized as a result of its false advertising and unfair competition. *See* 15 U.S.C. § 1117(a). The Court may decide disgorgement, or may allow the jury to decide. *Id.* ("The court shall assess such profits and damages or cause the same to be assessed under its direction.")

The "intent" of the Lanham Act is to "protect persons engaged in such commerce against unfair competition [and] to prevent fraud and deception in such commerce." 15 U.S.C. § 1127. Accordingly, one of the goals of § 1117(a) is to make violations of the Lanham Act "unprofitable." *Maltina Corp. v. Cawy Bottling Co.*, 613 F.2d 582, 585 (5th Cir. 1980). To recover ANI's unjust enrichment, Arbor need not show it would have made those same profits but for ANI's Lanham Act violations:

> Even when a plaintiff cannot quantify its losses with sufficient certainty to recover damages, it may still be entitled to . . . disgorgement of the defendant's ill-gotten profits under § 1117(a).

Lexmark Int'l, Inc. v. Static Control Comp., Inc., 572 U.S. 118, 135-36 (2014); *see also Mishawaka Rubber & Woolen Mfg. Co. v. S.S. Kresge Co.*, 316 U.S. 203, 207 (1942) (trademark infringer should not be allowed to retain its "windfall" profits).

While the Eighth Circuit previously imposed a willfulness requirement, *Minnesota Pet Breeders, Inc. v. Schell & Kampeter, Inc.*, 41 F.3d 1242, 1246-47 (8th Cir. 1994), the Supreme Court recently rejected that gloss on the Lanham Act. *See Romag Fasteners, Inc. v. Fossil, Inc.*, 140 S. Ct. 1492, 1497 (2020) (willfulness a relevant, but not necessary, consideration for disgorgement). Thus, disgorgement may be appropriate to (1) remedy Arbor's actual losses, (2) deter ANI's false advertising and unfair competition, and (3) prevent ANI from being unjustly enriched. *Minnesota Pet breeders,* 41 F.3d at 1246-47.

"In assessing profits the plaintiff shall be required to prove defendant's sales only; defendant must prove all elements of cost or deduction claimed." 15 U.S.C. § 1117(a). ANI also has the burden to prove apportionment if it claims not all profits resulted from the false advertising. *Rexall Sundown, Inc. v. Perrigo Co.*, 707 F. Supp. 2d 357, 359 (S.D.N.Y. 2010). Here, the evidence will show that ANI made about $20 million in unjust enrichment due to its false advertising and unfair competition.

III. UNRESOLVED ISSUES AT PRETRIAL STAGE

Because of the Court's rulings on ANI's motions to dismiss and for summary judgment, relatively few issues beyond ANI's liability and the amount of the award remain for resolution. Both parties have submitted motions *in limine*, including *Daubert* motions. Following a plaintiff's verdict, Arbor anticipates asking this Court to determine that this is an "exceptional case" pursuant to 15 U.S.C. § 1117(a), allowing the Court to award Arbor its reasonable attorneys' fees. E.g., *Safeway Transit LLC v. Discount Party Bus, Inc.*, 954 F.3d 1171, 1182 (8th Cir. 2020) (construing *Octane Fitness, LLC v. ICON*

Health & Fitness, Inc., 572 U.S. 545, 554 & n.6 (2014) (potential factors for evaluating whether case is exceptional include defendant's "'motivation, objective unreasonableness (both in the factual and legal components of the case) and the need in particular circumstances to advance considerations of compensation and deterrence'"). Section 1117(a) also allows the Court to award enhanced damages, including up to treble damages for lost profits. Depending on the award, Arbor may seek enhanced damages.

Arbor also will seek injunctive relief from the Court, as requested in its Complaint, and as allowed by the Lanham Act, 15 U.S.C. § 1116. Notably, Congress recently amended the Lanham Act to expressly create a presumption of irreparable harm upon a finding of a violation of the statute:

> ***A plaintiff seeking any such injunction shall be entitled to a rebuttable presumption of irreparable harm*** upon a finding of a violation identified in this subsection in the case of a motion for a permanent injunction or upon a finding of likelihood of success on the merits for a violation identified in this subsection in the case of a motion for a preliminary injunction or temporary restraining order.

15 U.S.C. § 1116(a) (emphasis added), *as amended*, Trademark Modernization Act of 2020, The Consolidated Appropriations Act, 2021, Pub. L. 116-260, § 226, 134 Stat. 2208 (2020)).

In its advertising, including using a letter authored by its counsel, ANI falsely accused Arbor of misrepresenting the facts regarding ANI's false and misleading advertising of its EES product as FDA-approved and an AB-rated generic for Arbor's products. In addition to corrective advertising alerting customers of ANI's EES product shipped prior to the FDA's November 2, 2018 approval, Arbor may ask the Court to

require ANI to mitigate the damage to Arbor's reputation by acknowledging that ANI, rather than Arbor, had presented false information.

Finally, ANI raised a bare-bones "unclean hands" affirmative defense in its Answer, Dkt. 49 at Fourth Affirmative Defense. As Magistrate Judge Erickson explained in *Transclean Corp. v. Bridgewood Servs., Inc.*:

> The doctrine of unclean hands, which has its roots in the maxim "he who seeks equity must present himself in court with clean hands," *Manhattan Medicine Co. v. Wood*, 108 U.S. 218, 225 (1883), may arise when a party, who seeks equitable relief against a competitor's false advertising, has itself made false representations about its product to the public.
>
> **To successfully avail itself of the doctrine of unclean hands under Federal law, a defendant must show that the plaintiff committed wrongdoing that is directly related to the claim which it has asserted, and that the plaintiff's wrongdoing injured the defendant**. *See, Calloway v. Partners National Health Plans*, 986 F.2d 446, 450 (11th Cir. 1993), citing *Mitchell Bros. Film Group v. Cinema Adult Theater*, 604 F.2d 852, 863 (5th Cir. 1979). "Under Minnesota law, the doctrine of unclean hands will be invoked only to deny equitable relief to a party whose conduct has been unconscionable by reason of a bad motive or where the result induced by that party's conduct will be unconscionable either in the benefit to that party or in the injury to others." *Foy v. Klapmeier*, 992 F.2d 774, 779 (8th Cir. 1993).

77 F. Supp. 2d 1045, 1096 (D. Minn. 1999) (emphasis added, other citations omitted), aff'd in part and vacated in part on other grounds, 290 F.3d 1364 (Fed. Cir. 2002).

Accordingly, to send an unclean hands defense to the jury, ANI must have evidence to show that: (1) Arbor engaged in willful, egregious, or unconscionable conduct; (2) the conduct directly relates to the merits of the controversy between the parties; and (3) ANI was injured by that conduct. *Id.*; *accord, Mitchell Bros. Film Grp. v. Cinema Adult Theater*, 604 F.2d 852, 863-64 (5th Cir. 1979); *see also Saxon v. Blann*,

968 F.2d 676, 680 (8th Cir. 1992) (citing *Mitchell* with approval, stating: "The defense does not apply where plaintiff's misconduct is not directly related to the merits of the controversy between the parties, but only where the wrongful acts affect the equitable relations between the parties with respect to the controversy."); *Prow v. Medtronic, Inc.*, 770 F.2d 117, 122 (8th Cir. 1985) (citing *Mitchell* with approval, stating: "even assuming arguendo Medtronic's actions were inequitable, such misconduct must bear some relation to the merits of the case").

Arbor is unaware of any possible evidence that could made this showing. As Arbor understands it, ANI's theory of "unclean hands" is based on Arbor's communications with thirty parties about ANI's false advertising and unfair competition. In essence, ANI argues that because it purportedly did not engage in false advertising and unfair competition, Arbor was not telling the truth, and therefore its hands are unclean. But this has nothing to do with "unconscionable" conduct, and is merely a different way of saying that because ANI supposedly is not liable under the Lanham Act, Arbor should be barred from raising its Lanham Act claims.

In short, Arbor contents that ANI will fail to present sufficient facts to state a cognizable defense of unclean hands. Arbor therefore anticipates bringing a motion for judgment at the conclusion of the evidence to strike this affirmative defense.

IV. ESTIMATED TRIAL LENGTH

Arbor estimates that trial will take 10 business days, including jury selection and charge.

Dated: July 29, 2021

Respectfully submitted,

s/Andre Hanson

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